



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/726,856

12/02/2003

Sharat Singh

033.06-1US

5950

33603 7590 10/02/2007
MONOGRAM BIOSCIENCES
345 OYSTER POINT BLVD
SOUTH SAN FRANCISCO, CA 94080

EXAMINER

TUNG, JOYCE

ART UNIT

PAPER NUMBER

1637

MAIL DATE

DELIVERY MODE

10/02/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/726,856

Applicant(s)

SINGH ET AL.

Examiner

Joyce Tung

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11, 12 and 14-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-12 and 14-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The applicant's response filed 7/23/07 to the Office action has been entered.

Claims 11-12, and 14-20 are pending.

The finality of the Office action mailed 2/28/07 is withdrawn.

Applicant's arguments in the response filed 7/23/07 with respect to claims 11-12 and 14-20 have been considered but are moot in view of the new ground(s) of rejection.

1. Claims 11-12 and 14-20 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,686,152 since the response was not filed the terminal disclaimer.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1637

3. Claims 11-12 and 14-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grossman et al. (5470705, issued November 28, 1995) in view of Hall et al. (5,994,049, issued Nov. 30, 1999).

Grossman et al. disclose a method of detecting a plurality of different sequences in a target sequence involving the use of a plurality of sequence probes (See column 2, lines 54-56). The probe used in the method has the features of the electrophoretic probe cited in claims 14 and 19. The probe includes a binding polymer, a polymer chain that imparts to that probe, a distinctive ratio of charge/translational frictional drag and a reporter attached to the binding polymer (See column 20, lines 52-57). The binding polymer is an oligonucleotide including at least 10-20 bases allowing hybridization to the target polynucleotide (See column 6, lines 66-67 and column 7, lines 1-10). This teaching is inherent that the target polynucleotide is in the range of from 5-100 polynucleotides as recited in claim 15. Other binding polymers are analogs of polynucleotides, such as deoxynucleotides with a thiophosphodiester linkage (See column 7, lines 11-19). The polymer chain has a ratio of charge/translational frictional drag, which is evidenced by a distinctive electrophoretic mobility in a non-sieving matrix (See column 7, lines 50-64). The polymer chain can be polyethylene oxide (PEO) or a polypeptide chain where the chains are attached to different-sequence binding polymers (See column 3, lines 11-18). The teachings suggest that the charge/translational frictional drag consists of carbon, hydrogen, oxygen, phosphorus, nitrogen, sulfur and boron. The charge of the polymer is the total net electrostatic charge of the polymer at a given pH (See column 6, lines 15-16). It is inherent that the probes have a positive charge or a negative charge based upon the given pH. The label refers

Art Unit: 1637

to a fluorophore or chromophore (See column 6, lines 39-44). The features of Grossman et al.'s probe suggest the features of the claimed e-tag probe.

Grossman et al. do not explicitly disclose the molecular weight of the mobility modifier, which is 1 to 300 atoms or 30-3000 daltons, or from 35-1500 daltons. However, the binding polymer and polymer chain contribute to the mobility modifier of probe (See column 3, lines 55-64.). The polymer chain may be polyethylene oxide (PEO) or a polypeptide chain (See column 3, lines 11-18, column 7, lines 39-49). Since these molecules are small molecules, the teachings are inherent that the molecular weight of the mobility modifier would be from 1 to 300 atoms or from 30-3000 daltons or from 35-1500 daltons.

Grossman et al. also do not explicitly disclose that e-tag reporter has a molecular weight of from 150-10,000 daltons. However, the e-tag is defined in claims 14-15 and 19 containing a mobility modifier. As discussed in the previous paragraph regarding the molecular weight of mobility, the teachings of a mobility modifier read on the limitation regarding the molecular weight of the e-tag.

Grossman et al. do not explicitly disclose a capture agent that specifically binds the capture ligands of the electrophoretic probes and confers on the undigested electrophoretic probes a charge that causes the undigested electrophoretic to migrate upon electrophoretic separation in a direction opposite of that of the e-tag reporters, thereby excluding said undigested electrophoretic probes from the electrophoretic separation of the released e-tag as recited in claim 11, and the capture ligand and the capture agent recited in claims 17-18.

Hall et al. disclose a capture ligand is biotin or antibody and capture agent is avidin or antigen (See column 9, lines 3-9 and column 68, lines 23-28). Hall et al. also disclose that the

Art Unit: 1637

cleaved probe may be separated from uncleaved probe using a charge reversal technique (See column 124, lines 66-67 and column 125, lines 1-2) in which cleaved probe and uncleaved probe can migrate in opposite directions in gel electrophoresis (See column 125, lines 27-29 and column 147, lines 36-41).

One of ordinary skill in the art would have been motivated to apply the capture ligand and capture agent as taught by Hall et al. because Hall et al. disclose that capture may facilitate the measuring of incorporated label (See column 68, lines 26-29). Moreover, one of ordinary skill in the art would also have been motivated to apply a charge reversal technique to separate cleaved eTag reporter from uncleaved electrophoretic probe because an abundance of uncleaved probe can be supplied to drive the hybridization step of the probe based assay and unconsumed probe can be subtracted from the result to reduce background (See column 125, lines 36-41). It would have been prima facie obvious to apply the capture ligand and agent as recited in claims 17-18 and separate the eTag reporter from undigested electrophoretic probe upon electrophoretic separation in a direction opposite of the eTag reporter.


Summary


4. No claims are allowed.
5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1637

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Joyce Tung 
September 20, 2007


KENNETH R. HORLICK, PH.D.
PRIMARY EXAMINER
10/1/07